Statement PhRMA

Statement of the Pharmaceutical Research and Manufacturers of America ("PhRMA")
Opposing Michigan House Bills 4044, 4045, and 4046 (HB 4044, HB 4045, and HB 4046)
February 14, 2007

Position: PhRMA respectfully opposes Michigan HB 4044, HB 4045, and HB 4046 because the bills would expand the liability of pharmaceutical manufacturers whose drugs are approved for efficacy and safety by the United States Food and Drug Administration, create a retroactive statute of limitation for causes of action based on drug products, and add an additional cause of action under the Michigan consumer protection laws. The expansion of these laws could jeopardize the research and development of new and improved life saving drugs.

House Bill 4044 would repeal the existing defense to liability (Section 2946(5)) to which a drug manufacturer is entitled for its drugs that are approved for safety and efficacy by the United States Food and Drug Administration (FDA).

House Bill 4045 would establish a retroactive statute of limitations for causes of action based on drug product liability that could have been brought after January 1, 1996, but were barred by Section 2946(5). Together HB 4044 would repeal the law passed in 1996 and HB 4045 would establish a retroactive statute of limitations that would allow a plaintiff to bring an action to up to three years after the effective date of an amendatory act (HB 4044) that repeals Section 2946(5).

House Bill 4046 would amend Michigan's consumer protection law to add a cause of action for failing to accurately represent the risks involved in the intended use of a prescription or over-the-counter drug or medication, herbal product, dietary supplement, or botanical extract.

PhRMA opposes these bills that are aimed directly at pharmaceutical drug manufacturers. Clearly, the intent of the legislation is not to protect or even assist Michigan residents in their search for recourse if injured by a prescription drug. It is, instead, an effort by the trial bar to open the floodgates for litigation against the drug industry. Even a quick glance at the provisions in these bills makes this scheme transparent. The bills remove a defense for FDA approved drugs; offer a retroactive date for filing so that patients allegedly injured by drugs as far back as 1996 could bring an action against a drug maker for the next three years; and creates an additional cause of action against, among others, manufacturers of FDA approved drugs under the state's consumer protection law.

THE FDA SHOULD DETERMINE THE SAFETY OF PRESCTIPTION DRUGS - NOT A JURY

Under federal law, the FDA has the authority to review and approve prescription medicines. This includes labeling and advertising requirements for each drug. This preemption exists to ensure that patients nationwide have the benefit of the world's best safety standard. Having one agency controlling drug oversight ensures that if it deems any medicine unsafe, it would not allow that medicine to be prescribed or administered to patients. It should be recognized that even with FDA oversight, no medication is risk-free. This is why by law, every drug must list the known common and even rare side effects.

Everyday the FDA balances the needs and hopes of patients waiting for new treatments against the need to ensure that the medicines a patient might receive are safe and effective. Repealing the FDA defense implies that a drug researcher must know every possible risk before a drug can be available to patients. That is simply not possible and doing so would keep millions of patients waiting unnecessarily for medicines to save their lives or to improve the quality of their life. It is the responsibility of the patient's health care professional to inform the patient of potential side-effects and to determine whether the benefits of that drug outweigh the risks for that

patient.

Under existing Michigan law, if an injured patient believes that a drug maker may have acted fraudulently or misrepresented safety information, they can go to the FDA and share those concerns. If the FDA finds that a company misrepresented its drug to the FDA or withheld information about the drug in order to win approval, patients may sue. Existing law ensures that trial lawyers have a just reason before starting endless rounds of lawsuits which add to the growing cost of healthcare. Thus, Michigan residents have recourse available to them if they believe that they have been injured by a prescription drug. To date, it is unclear whether any Michigan resident has alleged that a prescription drug caused an injury and petitioned the FDA to determine whether the manufacturer acted fraudulently or misrepresented safety information to get that drug approved. If Michigan patients have not felt the need to petition the FDA then there is no reason for the Michigan legislature to do so at this time.

THE CONSTITUTIONAL CONCERN WITH RETROACTIVITY

House Bill 4045 would reopen the statute of limitations for any claim that could have been brought after January 1, 1996. Thus, HB 4045 would create liability for medication sales that predate the enactment of HB 4044 by more than ten years and that were protected at the time by law. This retroactive creation of liability for past conduct presents serious concerns under both the U.S. and Michigan Constitutions.

The U.S. Supreme Court has recognized that there is a "presumption against retroactive legislation." Basic considerations of fairness dictate that individuals have the opportunity to know what the law is and to conform their conduct accordingly. Such expectations should not be disrupted.[1] Thus, retroactive legislation is constrained by the Due Process Clauses of the United States and Michigan constitutions.[2]

Not all retroactive legislation is unconstitutional but retroactive changes that create new liability are unconstitutional. The U.S. Supreme Court has found that such retroactive changes unconstitutionally deprive a defendant of its property without due process of law in violation of the Fifth Amendment.[3] The Michigan Supreme Court agrees, recognizing that laws are unconstitutional when they either "create a new cause of action" or "impose a new liability upon the defendant where none existed before."[4]

Retroactive repeal would create new liability for conduct that was previously protected. The defense for drug manufacturers was designed to protect companies from uncertainty and fear surrounding product liability which could inhibit the development and introduction of new products aimed at preventing and treating illness and disease.[5] HB 4045 would reach back in time to remove this certainty and protection. This retroactive removal of protection – to create wide-ranging new liability for past conduct – presents serious constitutional questions under the Michigan and United States Constitutions.

Repealing the FDA defense for FDA approved drugs, making the repeal retroactive, and creating a new cause of action against pharmaceutical manufacturers is an open invitation for the trial lawyers to open their "motel" clinics and recruit litigants, whether patients have been harmed or not. This can hurt all businesses and the overall economic growth of the state.

For the reasons stated above, PhRMA opposes the passage of Michigan HB 4044, HB 4045, and HB 4046.

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA companies are

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[1] *Landgraf v. USI Film Prods., 511 U.S. 244, 265 (1994).*

[2] *See Gen. Motors Corp. v. Romein*, 503 U.S. 181, 191 (1992); *Romein v. Gen. Motors Corp.*, 436 Mich. 515, 525 (1990).

[3] *William Danzer & Co. v. Gulf & S.I.R. Co.*, 268 U.S. 633, 637 (1925).

[4] *Rookledge v. Garwood*, 340 Mich. 444, 456 (1954).

[5] House Legislative Analysis Section, *Products Liability, Torts: Senate Bill 344* 1 (1995).

leading the way in the search for new cures. PhRMA members alone invested an estimated $43 billion in 2006 in discovering and developing new medicines. Industry wide research and investment reached a record $55.2 billion in 2006.